

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
ST. JOSEPH DIVISION**

VetBridge Product Development Subsidiary I
(NM-OMP), LLC,

Plaintiff,

v.

NewMarket Pharmaceuticals, LLC,

Defendant.

Case No. 5:18-cv-06147-BCW

JURY DEMAND

**DECLARATION OF MARK RIDALL IN SUPPORT OF DEFENDANT
NEWMARKET PHARMACEUTICALS, LLC'S MOTION TO TRANSFER TO
THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY
AND SUGGESTIONS IN SUPPORT OF ITS MOTION TO TRANSFER**

I, Mark Ridall, hereby declare as follows:

1. I am President and Chief Executive Officer of NewMarket Pharmaceuticals, LLC ("NewMarket") which is Defendant in this action. I submit this Declaration in support of NewMarket's Motion to Transfer to the United States District Court for the District of New Jersey and Memorandum In Support of Their Motion to Transfer. I make the statements in this Declaration from personal knowledge and if called to testify, could do so competently.

2. NewMarket is a limited liability company, organized and existing under the laws of Delaware. NewMarket is in the business of developing animal pharmaceuticals. NewMarket is headquartered in Trenton, N.J. where it conducts virtually of its business including the signing of any contracts. NewMarket has four members three of whom reside in New Jersey and one that resides in Florida. NewMarket does not have any offices in the State of Missouri or in any other state for that matter. NewMarket maintains all its business records at its offices in Trenton,

N.J. NewMarket is required to maintain all materials associated with its new animal drug application in a secure location with controlled access. NewMarket maintains these materials, most of which are in hard-copy, at its headquarters in Trenton, N.J. NewMarket does not own any real estate, bank accounts or other property in Missouri. NewMarket does not purposefully direct any marketing or sales activities specifically toward Missouri.

3. NewMarket does not currently sell any products or have incoming revenue. In order to operate we must obtain funding from outside sources. We refer to this stage of the company as “pre-revenue.”

4. NewMarket is the designer, developer and owner of a drug for use in horses referred to as Omeprazole DSI Products. The material aspects of NewMarket’s drug was developed in New Jersey. This product is NewMarket’s first attempt to obtain approval from the Food and Drug Administration Office of Veterinary Medicine (“FDA/CVM”). NewMarket expects to begin generating revenue when upon approval of its Omeprazole DSI Product.

5. For a veterinary pharmaceutical product to be marketed and sold, the FDA/CVM has to first approve the product to ensure that it is safe and effective. The process begins with the filing of a new animal drug application (“NADA”). The drug sponsor collects information about the manufacturing, safety, and effectiveness of the new drug. The sponsor typically needs to conduct studies to develop this information. For any studies that are performed, the sponsor analyzes the results which are included in the application. A new animal drug sponsor may hire, and often does hire, an independent CRO to assist in the preparation of clinical trial management services related to a NADA. CRO’s are hired, in large part, because they are highly regulated by the federal government and held to the strictest standards of impartiality. The NADA, is reviewed by a team of FDA/CVM personnel, including veterinarians, animal scientists, biostatisticians, chemists, microbiologists, pharmacologists, and toxicologists. If the FDA/CVM

determines that the drug is, inter alia, safe and effective, the FDA/CVM approves the NADA and the drug can be legally marketed and sold.

6. A NADA includes several major technical components or “sections” such as: (1) Chemical Manufacturing and Controls (“CMC”); (2) Target Animal Safety; (3) Effectiveness; (4) Human Food Safety; and (5) Environmental Impact. A complete application also includes minor sections for Labeling and All Other Information as well as a Freedom of Information document. The FDA/CVM allows for the major technical sections to be submitted in phases but will not approve an application until all phases have been completed and individually approved. The minor sections may not be submitted until the major sections are deemed approvable.

7. NewMarket began the approval process when it filed the CMC section on January 26, 2017. The remaining sections of the NADA – the Target Animal Safety and Effectiveness sections – are based on the clinical trial data, which has been withheld by VetPharm. Without the clinical trial data, the remaining sections of the NADA cannot be submitted and the approval process has stopped.

8. On June 27, 2014 NewMarket entered into an agreement with VetBridge whereby NewMarket received \$4 million in funding and VetBridge received a limited right to distribute NewMarket’s drug. VetBridge’s distribution right was limited to the U.S. and limited to use in animals. VetBridge drafted the VetBridge Agreement and it was signed, by me for NewMarket, at NewMarket’s offices in Trenton, N.J. Prior to entering into the VetBridge Agreement, VetBridge members and NewMarket entered into several non-disclosure agreements (“NDA’s”) that, inter alia, precluded the disclosure of confidential information related to the project to be disclosed to non-parties.

9. When NewMarket entered into the agreement with VetBridge both parties estimated that the total cost for obtaining market approval would be \$4 million. On September 9,

2016, I sent VetBridge c/o Kevin Speltz President the letter attached as **Exhibit 1**. The letter explains why the cost of marketing approval had significantly exceeded the originally budgeted amount. Page 4 of the letter details the original budget vs the, at that time, current costs. In the letter I ask for additional funds to cover the increased costs of the obtaining marketing approval. VetBridge declined. To date, the cost of the project has exceeded \$8 million. Additional funds are necessary to complete the approval process.

10. To the best of my recollection, VetBridge was formed by at least pharmaceutical distributors including AHII/Paterson Veterinary Supply Inc. (of Mendota Heights, Minnesota), MWI Veterinary Supply (of Boise, Idaho), MidWest Veterinary Supply (of Lakeville, Minnesota), Clipper Distributing (of Saint Joseph, Missouri) and Victor Medical Co. (of Lake Forest, California).

11. On December 22, 2014, NewMarket and VetPharm entered into the Master Services Agreement. Attached as **Exhibit 2** is the first and last page of the Confidential VetPharm Agreement. The full document has been filed under seal in the district court litigation in New Jersey. The purpose of the VetPharm Agreement was for VetPharm to provide “clinical trial support services” to companies that are “developing new animal health products” and, in return, NewMarket agreed to “retain the services of VetPharm from time to time to provide clinical trial management services in connection with certain clinical research programs NewMarket is conducting”. VetPharm drafted the VetPharm Agreement and each page of the Agreement contains the phrase “VetPharm, Inc. CONFIDENTIAL” at the bottom. The VetPharm Agreement was signed at NewMarket’s offices in Trenton, N.J.

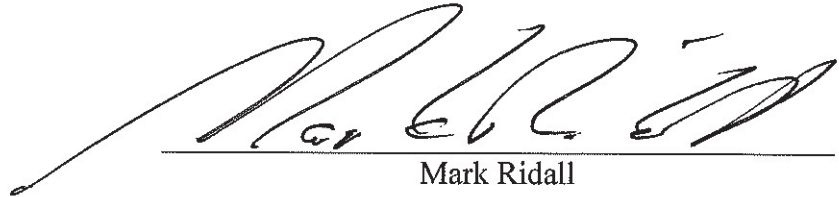
12. Attached to this Declaration as **Exhibit 3** is a true and accurate copy of an email exchange, dated March 22, 2016, that I had with the President of VetBridge Kevin Speltz. The exchange is self-explanatory. I told VetBridge to not communicate with VetPharm. Dave Rock

(“Rock”) gave a similar instruction to VetPharm. This was the first time I recall being made aware that representatives from VetPharm had inappropriately contacted representatives from VetBridge. Such contact is wholly improper and could potentially result in the entire study being thrown out by the FDA/CVM.

13. I repeatedly asked VetBridge for all communications with VetPharm but VetBridge was not forthcoming and even repeatedly denied that any such communications took place. But documents from the arbitration with VetPharm show that VetBridge disregarded my clear instructions and engaged with communications with VetPharm. I believe further discovery including, emails, text messages and phone records would reveal many more communications took place.

14. Attached to this Declaration as **Exhibit 4** is a true and accurate copy of an email exchange I had with VetPharm President Kevin Speltz dated August 9, 2017 and August 14, 2017. The exchange is self-explanatory.

15. I swear under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge and that this Declaration was executed on this 12th day of October 2018 in New York, New York.



Mark Ridall

Ridall Exhibit 1



September 9, 2016

VetBridge Product Subsidiary I, LLC
c/o Kevin Speltz
1302 S. 59th St.
St. Joseph, MO 64507

Re: Exclusive Distribution and License Agreement (the "Agreement")

Dear Kevin:

On June 27, 2014 NewMarket Pharmaceuticals LLC ("NewMarket" or "we") and VetBridge Product Development Subsidiary I, LLC ("VetBridge" or "you") entered into the Agreement wherein NewMarket was to develop, manufacture and act as the Drug Sponsor with the FDA CVM ("FDA") of the Omeprazole DSI composition for animals ("Omeprazole Products") and VetBridge was to be the exclusive distributor and funder of the products in the United States and its territories.

Since that date, you have funded Four Million Dollars (\$4,000,000) and we have taken steps and studies to get FDA approval for the Omeprazole Products.

At the signing of our Agreement, the FDA position was for a single product with a flexible label approved for both treatment and prevention of gastric ulcers in horses, which would have required a single safety study and a single efficacy study to receive both claims. During a teleconference with the FDA after the signing of our Agreement (in which Doug Rupp participated), the FDA changed its position and determined the flexible label strategy was no longer appropriate and should be split into two products, one for "Treatment" and one for "Prevention" each requiring its own clinical efficacy study. This change in position immediately increased the projected cost of just the clinical efficacy studies by over \$500,000 as described in the attached chart (Page 4, line 2).

Further, our clinical trial contractor, VetPharm, forecast that ten percent (10%) of the horses screened for inclusion in the Treatment study would be disqualified for various reasons. The actual number has turned out to be 10x the number of horses anticipated in the budget, and over 50% of the total number of horses screened for inclusion in the Treatment study. The cost of these "screen failures" is significant, as each horse must have a series of diagnostics performed first in order to determine eligibility. These exclusions have led to Treatment efficacy study costs being more than double what was originally forecast, consequently the total Treatment efficacy study cost is now estimated at \$1,286,000 for an overrun of \$674,000 from the revised budget.

These aforementioned overruns with VetPharm led us to our discussions beginning late last year for additional funding in anticipation of exceeding VetPharm costs. These overruns have led to efficacy study costs being more than double what was originally forecast, as total efficacy study costs, for both Treatment and Prevention, are presently estimated at \$2,399,000 for an overrun of \$977,000 from the revised two study budget.

In addition to exceeding their development quote by over \$400,000 even accounting for a contingency we built into our original budget (Page 4, line 9), Catalent, which has been our contract manufacturer since the inception of our Agreement, has made new demands as of April 2016 upon us to pay a monthly retainer fee ("Capacity Reservation Fee") to keep the manufacturing facility open in the United States. As this site is the only U.S. site able to manufacture the products, we opted to enter into this Agreement as it would save at least a year in approval date by avoiding technical transfer to another Catalent site and, perhaps more importantly, would preserve a site capable of producing future products containing active ingredients not approved for use in humans. The cumulative effect of exceeding the development costs and the capacity reservation fees will result in more than \$2,000,000 in additional costs above the amount forecast for development.

We now wish to advise that we are seeking to raise adequate funds to address the projected additional costs and develop the Omeprazole Products (including Treatment and Prevention) per the Agreement and desire for the parties to get back to a good faith working relationship.

To that end, are willing to put the following concepts in writing for your information and consideration:

1. Bryan Ridall shall be appointed the point of contact for Kevin Speltz and VetBridge's FDA consultant continuing rights regarding the Omeprazole Products to review all books, records, documents, debts, etc. related to the Omeprazole Products project subject to confidentiality.
2. NewMarket acknowledges that VetBridge has the exclusive rights in the United States under the Agreement to fund and distribute the veterinary products containing omeprazole developed by NewMarket. In addition to the review of records stated above, Dr. Dave Rock will meet with VetBridge to present an update on the scientific findings and provide an update on the approval process.
3. A meeting will be scheduled with Kevin Speltz, and any other VetBridge member(s) desiring to be present, for Dr. Dave Rock to provide an update on the technical and scientific findings regarding the performance of omeprazole in the clinical studies and to update VetBridge on the regulatory status of the submission(s). We propose this meeting take place no later than 31 October 2016.
4. As noted above, unanticipated expenses were incurred, and continue to be incurred, developing the Treatment product. These additional costs have led to an increase in the forecasted cost of production. NewMarket and VetBridge will, as

per the Agreement, adjust the transfer price accordingly after VetBridge has the opportunity to review these extra expenses.

5. The NADA for "Prevention" will be an addition to the NADA for "Treatment" and has different concerns surrounding the intellectual property landscape. Should the parties determine to pursue the Prevention claim, these additional expenses will need to be negotiated with VetBridge as part of the transfer price.
6. NewMarket and VetBridge will meet no later than 31 October 2016 to discuss VetBridge's marketing plan, packaging suggestions, sales forecasts, and other commercialization plans for the Omeprazole Products.

We hope this letter satisfies you that there will be transparency going forward and with strong and continuing communications between Bryan Ridall and Kevin Speltz. All parties can stay abreast of Omeprazole Products development and the parties can look forward to a profitable future as we move this project into its final stages.

Sincerely yours,

NEWMARKET PHARMACEUTICALS LLC

By: 
Mark Ridall, CEO

cc: Thomas H. Stahl (via e-mail)
Tom Overbay (via e-mail)

Project Budget Chart

Line #	Description	Original Budget ¹	Treatment Product ²	Prevention Product ³	Total
1	Efficacy Study	\$ 900,000	\$ 1,286,000	\$ 1,113,000	\$ 2,399,000
2	Revised Budget	\$ -	\$ 612,000	\$ 810,000	\$ 1,422,000
3	VetPharm Overrun	\$ -	\$ 674,000	\$ 303,000	\$ 977,000
4	Safety Study	\$ 800,000	\$ 571,000	☐ ⁵	\$ 571,000
5	CMC Section	\$ 955,000	\$ 1,400,000	☐	\$ 1,400,000
6	Catalent Quote	\$ 715,000	\$ 715,000	☐	\$ 715,000
7	Contingency ⁶	\$ 185,000	\$ 185,000	☐	\$ 185,000
8	API	\$ 55,000	\$ 75,000	☐	\$ 75,000
9	Catalent Overrun ⁷	\$ -	\$ 425,000	☐	\$ 425,000
10	All Other	\$ 1,345,000	\$ 3,307,000	\$ 376,000	\$ 3,683,000
11	Catalent License Fee	\$ 800,000	\$ 800,000	☐	\$ 800,000
12	ADUFA Sponsor Fee	\$ 400,000	\$ 516,000 ⁸	☐	\$ 516,000
13	Consultants	\$ 145,000	\$ 200,000	\$ 25,000 ⁹	\$ 225,000
14	pK Study ¹⁰	\$ -	\$ 91,000	-	\$ 91,000
15	Capacity Reservation Fee ¹¹	\$ -	\$ 1,700,000 ¹²	-	\$ 1,700,000
16	ADUFA Application Fee	\$ -	\$ -	\$ 351,000 ¹³	\$ 351,000
17	TOTAL	\$ 4,000,000	\$ 6,564,500	\$ 1,489,000 ¹⁴	\$ 8,053,500

¹ The "Original Budget" column represents the original budget at time of contract signing in 2014 based on CRO quotes and CVM guidance.

² The "Treatment Product" column shows the actual costs incurred to develop the "treatment" product.

³ The "Prevention Product" column shows the current projected cost to finish development of the "prevention" product

⁴ Line 2 "Revised Budget" shows the revised budgets for the "treatment" and "Prevention" studies, following the change in position by the CVM in December 2014 to abandon the flexible label strategy.

⁵ ☐ Represents work done in support of "Treatment" product, which is expected to be applicable to "Prevention" product submission for FDA approval.

⁶ A contingency was built into our original forecast for anticipated overrun by Catalent.

⁷ Actual cost by Catalent to develop the product exceeded the forecast contingency by \$425,000, and their quote by \$610,000.

⁸ The increased ADUFA Sponsor Fee is due to the project continuing into 2017.

⁹ Estimate.

¹⁰ pK Study was an additional study requested by the CVM.

¹¹ New Catalent requirements of April 2016 in order to maintain US manufacturing.

¹² Estimate based on August 2017 approval. Each month there after increases this cost by \$250,000.

¹³ Estimated based on 2016 fees published by CVM

¹⁴ Estimate based on moving project forward promptly. Significant delay in pursuing "Prevention" product will result in significant increase to cost shown, and is subject to regulatory changes by CVM.

Ridall Exhibit 2

MASTER SERVICES AGREEMENT

This MASTER SERVICES AGREEMENT (the "Agreement"), by and between VetPharm, Inc., a New York corporation, with its principal executive office located at 349 West Commercial Street, Suite 2200, East Rochester, New York 14445 ("VetPharm") and NewMarket Pharmaceuticals, LLC, a Delaware company with its principal executive office at 621 Executive Drive, Princeton, New Jersey 08540 ("NewMarket") (individually, a "Party" and, collectively, the "Parties") shall become effective on the last date entered below (the "Effective Date").

WHEREAS, VetPharm is a contract research organization committed to improving the well-being of all companion animals by providing comprehensive clinical trial support services to pharmaceutical, nutrition, nutraceutical, and device companies which are developing new animal health products; and

WHEREAS, NewMarket is a global provider of veterinary pharmaceutical products; and

WHEREAS, NewMarket may wish to retain the services of VetPharm from time to time to provide clinical trial management services in connection with certain clinical research programs NewMarket is conducting (individually, a "Project"), in which case the terms and conditions for each such Project shall be set forth in a project addendum to be attached to this Agreement and incorporated herein by reference (individually, a "Project Addendum" and collectively, the "Project Addenda"); and

WHEREAS, VetPharm is willing to provide such services to NewMarket in accordance with the terms and conditions of this Agreement and the attached Project Addenda.

NOW, THEREFORE, for good and valuable consideration contained herein, the exchange, receipt, and sufficiency of which are acknowledged, the Parties agree as follows:

1. Services.

1.1 Services to be Provided by VetPharm. VetPharm hereby agrees to provide to NewMarket the services identified and described in the Services section of each Project Addendum attached to this Agreement (the "Services"). VetPharm shall perform the Services for each Project set forth in the applicable Project Addendum in compliance with (i) the protocol for the Project ("Protocol") which shall be made a part of the Project Addendum, (ii) this Agreement, (iii) the Project Addendum, (iv) standard operating procedures approved by NewMarket, and (v) applicable law and regulations issued pursuant thereto.

IN WITNESS THEREOF, this Agreement has been executed and delivered by the Parties by their duly authorized officers.

NEWMARKET PHARMACEUTICALS, LLC

VETPHARM, INC.

By: 

By: 

Name: David W. Rock, PhD

Name: Denni O. Day

Title: Vice President

Title: President / CEO

Date: 22 DEC 2014

Date: 22 DEC 2014

Ridall Exhibit 3

From: Mark Ridall <m.ridall@aborisah.com>
Subject: Re: Vet Pharm
Date: March 22, 2016 at 6:36:26 PM EDT
To: Kevin Speltz <KSpeltz@clipperdist.net>
Cc: "Tom Overbay (tom.overbay@gmail.com)" <tom.overbay@gmail.com>

Kevin.

I trust you had a nice trip.

At this time I can not give you permission to speak with VetPharm under the advice of council. We would consider direct contact with VetPharm interference with our existing contracts.

Let's talk tomorrow.

Mark

Sent from my iPhone

On Mar 22, 2016, at 5:04 PM, Kevin Speltz <KSpeltz@clipperdist.net> wrote:

Mark

As you are aware Denni from Vet Pharm has reached out and contacted myself and several of the VB members.

As President of Vet Bridge, I have a fiduciary responsibility to the organization and to the project we are working on with New Market.

I am requesting written permission from you to talk with Vet Pharm directly, per her request.

I believe it is in all of our best interest to have me be the contact for Vet Bridge and keep our project moving forward.

Thanks

Kevin Speltz

President

Clipper Distributing Company, LLC

1302 S 59th Street

St Joseph, MO 64507

816-364-5777 x100

kspeltz@clipperdist.net

Ridall Exhibit 4

From: Kevin Speltz <KSpeltz@clipperdist.net>
Subject: RE: Information request
Date: August 14, 2017 at 2:41:14 PM EDT
To: Mark Ridall <mridall@newmarketpharma.com>

Tom Stahl told me to decline this request.

We have addressed this in the past as you have noted in your email.

Thanks

Kevin Speltz
President
Clipper Distributing
1302 S 59th Street

St Joseph MO 64503
816-364-5777 x 100

From: Mark Ridall [<mailto:mridall@newmarketpharma.com>]
Sent: Wednesday, August 9, 2017 10:16 AM
To: Kevin Speltz <KSpeltz@clipperdist.net>
Subject: Information request

Kevin-

I hope you are well today!
I need your help with some information.

In early 2016 I sent you a request for all communications between VetPharm and anyone associated with VetBridge (that would include employees ,any of the ownership participants and counsel).At our meeting on May 6,2016 you and all the other participants (Cleary,Adent,Stahl Speltz) stated they had never spoken to VetPharm or any representative of that company. We are having difficulty getting document production from VetPharm at this point I would request to you that any communications, emails, phone calls, face-to-face meetings [ect.be](#) supplied to NewMarket ASAP. This request would include but not be limited to all participants in the ownership of VetBridge,their employees, and representatives as well as counsel.

Please consider this an official request.

Best regards,

Mark Ridall
CEO & Managing Partner

NewMarket Pharmaceuticals LLC
4 Pitcairn Avenue, Suite 4
Trenton, New Jersey 08628
t: [609.252.9600](tel:609.252.9600) ext. 101
mridall@newmarketpharma.com
www.newmarketpharma.com

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